Action No. 88-1467-A (E.D. Va. 1988), held that the PTO ruling was arbitrary and capricious. Shortly thereafter, PTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Ceftin is 1,559 days. Of this time, 677 days occurred during the testing phase of the regulatory review period, while 882 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* September 23, 1983. The applicant claims that the investigational new drug application (IND) for Ceftin became effective September 22, 1983. However, FDA records indicate that the IND became effective September 23, 1983.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act:* July 30, 1985. FDA has verified the applicant's claim that the new drug application (NDA) (known then as a Form 5 application) for Ceftin (NDA 50-605) was initially submitted July 30, 1985.

3. *The date the application was approved:* December 28, 1987. FDA has verified the applicant's claim that NDA 50-605 was approved December 28, 1987.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, PTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 12, 1989, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 10, 1989, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 6, 1989.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 89-8757 Filed 4-12-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket Nos. 89E-0086 and 89E-0087]

Determination of Regulatory Review Period for Purposes of Patent Extension; CERADON®

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Ceradon® (cefotiam hydrochloride) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of two patents which claim that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the antibiotic Ceradon® (cefotiam hydrochloride). Ceradon® is indicated for the treatment of the following when caused by susceptible strains of the designated microorganisms: lower respiratory tract infections, bronchitis and pneumonia, caused by streptococcus pneumoniae and haemophilus influenzae (ampicillin-susceptible strains). Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for Ceradon® (U.S. Patent Nos. 4,161,527 and 4,241,057) from Takeda Chemical Industries, Ltd., and requested FDA's assistance in determining the eligibility of these patents for patent term restoration. FDA, in a letter dated March 28, 1989, advised the Patent and Trademark Office that the human drug product had undergone a regulatory review period. The letter also stated that the active ingredient, cefotiam hydrochloride, represented the first permitted commercial marketing or use. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Ceradon® is 3,158 days. Of this time, 1,817 days occurred during the testing phase of the regulatory review period, while 1,341 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* May 10, 1980. FDA has verified the applicant's claim that the date the investigational new drug application (IND) for Ceradon® became effective was May 10, 1980.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act:* April 30, 1985. FDA has verified the applicant's claim that the date the new

drug application (NDA 50-601) was initially submitted to the FDA was April 30, 1985.

3. *The date the application was approved:* December 30, 1988. FDA verified the applicant's claim that NDA 50-601 was approved on December 30, 1988.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In each of its applications for patent extension, this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 12, 1989, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 10, 1989, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket numbers found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 5, 1989.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 89-8758 Filed 4-12-89; 8:45 am]

BILLING CODE 4160-01-M

Veterinary Medicine Advisory Committee; Amendment of Notice of Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending a notice that announces a public meeting of the Veterinary Medicine Advisory Committee. The amendment reflects a change in the location of the meeting. Notice of the April 25 and 26, 1989, meeting was published in the Federal Register of March 20, 1989 (54 FR 11445).

SUPPLEMENTARY INFORMATION: In FR Doc. 89-6426, appearing at page 11445 in the Federal Register of March 20, 1989, in the third column, under the heading "Veterinary Medicine Advisory Committee", the "*Date, time, and place*" paragraph is corrected to read "*Date, time, and place.* April 25 and 26, 1989, 8:15 a.m., Georgetown Room, Days Inn Congressional Park, 1775 Rockville Pike, Rockville, MD."

Dated: April 7, 1989.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-8761 Filed 4-12-89; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA-940-09-; CACA 7300 WR, CARI 01561 WR]

Termination of Small Tract Classification Nos. 263, 495; California

AGENCY: Bureau of Land Management, Interior.

ACTION: Termination of Small Tract Classification.

SUMMARY: This action terminates Small Tract Classifications Nos. 263 and 495 which classified public land for disposition pursuant to the Small Tract Act of 1938. The Small Tract Act of 1938 was repealed by the Federal Land Policy and Management Act, 90 Stat. 2743 dated October 21, 1976, therefore, the classification is moot. Removal of the classification will allow completion of two public sales held under Section 203 of the Federal Land Policy and Management Act.

FOR FURTHER INFORMATION CONTACT: Judy Bowers, BLM California State Office, 2800 Cottage Way, Room E-2841, Federal Office Building, Sacramento, California 95825 (916) 978-4815

1. Pursuant to the authority delegated by Appendix 1 of Bureau of Land Management Manual 1203 dated April 14, 1987, Small Tract Classification Nos. 263 and 495 are hereby terminated as to the following lands:

San Bernardino Meridian

Small Tract No. 495

T. 4 N., R. 14 W.,
Sec. 5, lot 22.

Small Tract No. 263

T. 5 N., R. 13 W.,
Sec. 6, lots 18, 20, 21, 22, 25, 26, 27, 28, 29, 30, 31, 32;
Sec. 7, lots 6, 7.

The areas described contain 179.67 acres.

2. The classification segregated the public lands from all other forms of appropriation under the public land laws, including location under the United States mining laws, but not leasing under the mineral leasing laws, pursuant to the Act of June 1, 1938 (52 Stat. 609; 43 U.S.C. 682a), as amended. The Small Tract Act of 1938 was repealed by Section 702 of the Federal Land Policy and Management Act of October 21, 1976 (90 Stat. 2789); the classification therefore no longer serves a useful purpose as to the land described above.

3. Accordingly, at 10 a.m. on April 11, 1989, the lands described in paragraph 1 will be opened to operation of the public land laws, generally, and the United States mining laws, subject to valid existing rights, the provisions of existing withdrawals and classifications, and the requirements of applicable law.

Dated: April 3, 1989.

Nancy J. Alex,

Chief, Lands Section Branch of Adjudication and Records.

[FR Doc. 89-8733 Filed 4-12-89; 8:45 am]

BILLING CODE 4310-40-M

[WY-030-09-4111-01]

Rawlins District Advisory Council; Meeting

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Notice of meeting of the Rawlins District Advisory Council.

SUMMARY: Notice is hereby given in accordance with Pub. L. 94-579 that a meeting of the Rawlins District Advisory Council will be held.

DATE: May 11, 1989.

ADDRESS: Comfort Inn, 1801 East Cedar Street, Rawlins, Wyoming.

FOR FURTHER INFORMATION CONTACT: Grant Petersen, Public Affairs Specialist or Dick Bastin, District Manager, Rawlins District, Bureau of Land Management, P.O. Box 670, Rawlins, Wyoming 82301, (307) 324-7171.

SUPPLEMENTARY INFORMATION: The meeting will be held at 10:00 a.m. at the Comfort Inn in Rawlins, Wyoming.

A public comment period will be held at 1:30 p.m. The agenda items for the meeting will include: Wildlife 2000, Cultural Resource Protection at Bairoil, Fencing, Recreation 2000, Election of Officers.

The meeting is open to the public. Anyone interested in attending the meeting and/or making an oral statement should notify the District